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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,236	04/28/2006	Holger Winter	2923-741	2529

6449 7590 02/01/2008

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EXAMINER	
STAPLES, MARK	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
02/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/560,236	WINTER ET AL.	
	Examiner	Art Unit	
	Mark Staples	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *10 and 13-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11, and 12* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-12 of Group I in the reply filed on 11/02/2007 is acknowledged. The traversal is on the ground(s) that the technical feature linking the claims is the structure of formula 1 of claim 1.

This is not found persuasive because this technical feature is not a special technical feature, as Rudert al. teach a structure of formula 1. Rudert al. teach the DRB-specific probe (see the legend to Figure 5) where M is FAM, M' is TAMRA, Z on the 5' end is independently the pyrimidine nucleotide C, Z on the 5' end is independently the pyrimidine nucleotide T, with n = n' = 1, where X in each case is an arbitrary nucleotide, and with m = 21. Therefore, the technical feature linking the inventions of Groups I-II does not consitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/02/2007.

2. Applicant's election with traverse in the reply filed on 11/02/2007 is acknowledged of the specie of formula 1 where $X_1 - X_2...X_m$ is designated as a probe sequence specific for the analyte PGK-1; M and M' are rhodamine green; n and n' are 5, Z is a pyrimidine nucleotide; m is 40; X is - O-; Y is =O; Y' is -OH; and R is -OH to begin the prior art search. Regarding B, this group defines the specificity of the probe and can be any of the nucleobases: adenine, guanine, cytosine, uracil or thymine. Applicant's argument that electing every variable X and every variable B would be meaningless is persuasive. Thus the requirement for election of every variable X and every variable B is withdrawn. Due to there being no requirement for election of the analyte, Applicant's designation of PGK-1 as the analyte is not considered. Thus, the specie of formula I for examination is where X and B are variable, where M and M' are rhodamine green; n and n' are 5, Z is a pyrimidine nucleotide; m is 40; X is - O-; Y is =O; Y' is -OH; and R is –OH.

Claim 10 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected specie, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/02/2007.

In summary, claims 1-9, 11, and 12 and the elected specie as noted above are pending and at issue.

Priority

3. It is noted that an English translation of the foreign German application 103 26 302.0 has not been provided.

Specification

4. The use of the trademarks RHODAMINE GREEN™, BODIPY™, and ALEXA™ have been noted in this application. They and any other trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is advised to scan the entire application to ensure trademark usage in all the places where it appears in the application is in compliance with the current office guidelines.

Claim Objections

5. Claim 7 is objected to because of the following informalities: the trademarks RHODAMINE™, BODIPY™, and ALEXA™ should be capitalized. Appropriate correction is required. It is noted that the generic terminology of "dyes" for these trademarks is properly recited in this claim.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-9, 11, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "nucleotide analog" in claims 1, 4, and 5 is an undefined term which renders the claim indefinite. The term "nucleotide analog" is not defined by the claim and the specification does not provide a limiting definition. As nucleotide analogs can encompass myriads of compounds comprising substantial to very few structural components of a nucleotide, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claims (MPEP § 2171 requirement (B)). Dependent claims 2,3, 6-9, 11, and 12 are thus indefinite as well.

9. The term "pyrimidine nucleotide analog" in claim 1 is an undefined term which renders the claim indefinite. The term "pyrimidine nucleotide analog" is not defined by the claim and the specification does not provide a limiting definition. As pyrimidine nucleotide analogs can encompass myriads of compounds comprising substantial to very few structural components of a pyrimidine nucleotide, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claim (MPEP § 2171 requirement (B)). Dependent claims 2-9, 11, and 12 are thus indefinite as well.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tyagi et al. (United States Patent No. 6,150,097 issued November 21, 2000), Weisburg et al. (United States Patent No. 6,110,678 issued August 29, 2000), and Nunnally et al. (1997).

Regarding claims 1, 4, 9, and 12 Tyagi et al. teach a probe of formula (I) (see SEQ ID NO: 5 in column 13 lines 17-19)

where Z is the pyrimidine nucleotide C,

where M and M' are fluorescent groups which can be fluorescein (see Figure 4)

and where M and M' are identical, that is the same, fluorescent group (see column 3 lines 45-48),

where in SEQ ID NO: 5 n is 1,

and m can be 7-140 and thus can be 40 (see claim 10).

Regarding claims 1, 4, 9, and 12 Tyagi et al. do not specifically teach a poly pyrimidine tail, that is, where n for Z is 5. Tyagi et al. do not specifically teach where the fluorophore labeling group is RHODAMINE GREEN™.

Regarding claims 1, 4, 11, 9, and 12 Weisburg et al. teach where Z_n is at least C_5 by teaching C_n where n is at least about 10 bases (column 8 Lines 36-59). Weisburg et al. teach that fluorophores well known in the art can be used on probes, but do not specifically teach where the fluorophore labeling group is RHODAMINE GREEN™.

Regarding claim 2, Weisburg et al. teach the further specie election of formula (II) where X is - O-; Y is =O; Y' is -OH; and R is –OH (see Structure 1 in column 13).

Regarding claims 3 and 6, Weisburg et al. teach thymidine 2' deoxynucleotides (see Example 1).

Regarding claim 5, Regarding claims 1, 4, and 9, Weisburg et al. teach where Z_n is at least T_5 by teaching T_n where n is at least about 10 bases (column 8 Lines 36-59).

Regarding claims 1, 4, 7- 9, and 12 Nunnally et al. teach fluorescein, as also taught by Tyagi et al. above, and that RHODAMINE GREEN™ may be substituted for fluorescein (see Table 1 and see the 1st full paragraph in the 2nd column on p. 2394). Nunnally et al. teach that the use of fluorescein in probes was well known (see 1st full paragraph on p. 2392).

Tyagi et al. teach pyrimidine nucleotides on the ends of a probe and teach identical fluorophores including fluorescein on the ends of probes. Weisburg et al. teach multiple pyrimidine nucleotides on the ends of probes and fluorescent labels on the ends of these. Nunnally et al. teach that the use of fluorescein was well known and that RHODAMINE GREEN™ may be substituted for fluorescein. Because both Tyagi et al. and Weisburg et al. teach well known fluorophores, it would have been obvious to one skilled in the art to substitute the well known fluorescein of Tyagi et al. as the fluorophore for the well known fluorophores of Weisberg to arrive at the claimed probe, but with fluorescein being the identical flurophore on each end (instead of RHODAMINE GREEN™). As Nunnally et al. teach RHODAMINE GREEN™ may be substituted for fluorescein, it would have been obvious to one skilled in the art to substitute RHODAMINE GREEN™ for the fluorescein of Tyagi et al. and Weisberg in order to achieve the predictable result of a probe having ends of poly pyrimidine nucleotides with RHODAMINE GREEN™ at the ends of each of these.

Conclusion

13. No claim is free of the prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
January 23, 2008

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
1/29/08